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10/780,267	02/17/2004	Donald Lynn Bissett	9176R	2224

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,267	BISSETT, DONALD LYNN	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-22,24-26 and 28-36* is/are pending in the application.

4a) Of the above claim(s) *6-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5, 21, 22, 24-26, and 28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted September 28, 2009 wherein claims 1 and 26 are amended and claim 4 is cancelled. This application is a continuation in part of US application 10/379252, now abandoned, filed March 4, 2003.

Claims 1, 3, 5-22, 24-26, and 28-36 are pending in this application.

Claims 6-20 are withdrawn from consideration as being directed to a non-elected invention.

Claims 1, 3, 5, 21, 22, 24-26, and 28-36 as amended are examined on the merits herein.

Applicant's amendment, submitted September 28, 2009, with respect to the rejection of instant claims 1, 3, 24, 26, and 32 under 35 USC 102(e) for being anticipated by Warren et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition be an emulsion. Therefore the rejection is withdrawn.

Applicant's arguments, submitted September 28, 2009, with respect to the rejection of instant claims 4, 5, and 35 under 35 USC 103(a) for being obvious over Warren et al. in view of Wright, have been fully considered and found to be persuasive to remove the rejection as Applicant has stated that Warren et al. was commonly owned

with the instant application at the time of invention and thus disqualified as prior art under 35 USC 103(c). Therefore the rejection is withdrawn.

Applicant's arguments, submitted September 28, 2009, with respect to the rejection of instant claim 30 under 35 USC 103(a) for being obvious over Warren et al. in view of Stuttgen et al., have been fully considered and found to be persuasive to remove the rejection as Applicant has stated that Warren et al. was commonly owned with the instant application at the time of invention and thus disqualified as prior art under 35 USC 103(c). Therefore the rejection is withdrawn.

Applicant's arguments, submitted September 28, 2009, with respect to the rejection of instant claims 28 and 29 under 35 USC 103(a) for being obvious over Warren et al. in view of Stack, have been fully considered and found to be persuasive to remove the rejection as Applicant has stated that Warren et al. was commonly owned with the instant application at the time of invention. Therefore the rejection is withdrawn.

Applicant's arguments, submitted September 28, 2009, with respect to the rejection of instant claims 32-34 under 35 USC 103(a) for being obvious over Warren et al. in view of Yu et al., have been fully considered and found to be persuasive to remove the rejection as Applicant has stated that Warren et al. was commonly owned with the instant application at the time of invention. Therefore the rejection is withdrawn.

Applicant's amendment, submitted September 28, 2009, with respect to the rejection of instant claims 1-3 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 1-2 and 4-16 of copending application 10/152925, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the composition be an emulsion, which is not an absorbent article as claimed in 10/152924. Therefore the rejection is withdrawn.

Commonly owned US application 10/977848 has been abandoned. Therefore the rejection of claims 1-5, 21-24, 31, 32, 35, and 36 under the doctrine of obviousness-type double patenting as claiming the same invention as this application is withdrawn.

The following rejections of record in the previous action are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 21, 23-24, 26 and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett et. al. (U.S. Patent No. 6,284,802; of record in previous action)

Bissett et. al. discloses the use of vitamin B3 compounds in skin care compositions. (Column 33, claim 3). Example 1 discloses a composition with 2% niacinamide, a vitamin B3 compound. (Column 30, lines 1-5; Column 16-17, section titled "Vitamin B3 compounds"). Water, glycerin and silicone fluids are disclosed in emulsions and are considered carriers. (Example 2). Hexamidine is disclosed as useful as an antimicrobial adduct. (Column 23, line 45-55). Bissett further discloses the use of anti-acne actives, peptides, scavengers and sunscreen additives. (Column 34, claim 6; See Column 16, section titled "Desquamation agents"; Column 18, titled "peptides"). Bissett further discloses ascorbyl glucosamine as an additive. (Column 15, lines 65-68). Glucosamine and panthenol are disclosed as a conditioning agents. (Column 25, lines 50-Column 26, line 5; Column 33, claim 4). Tocopherol acetate is disclosed as an anti-oxidant additive. (Column 19, lines 1-36). Retinoids (column 17 lines 39-65) peptides including carnosine (column 18 lines 27-42) anti-cellulite agents including caffeine (column 22 lines 42-47) and natural anti-inflammatory agents such as phytosterols. (column 22 lines 12-24) Example 4 in column 32 lines 15-40 includes butylated hydroxytoluene, which falls within the structure of new claim 36, as an ingredient.

Bissett does not exemplify a composition comprising hexamidine

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a skin care composition comprising hexamidine, and vitamin B3 and additional ingredients such as peptides, additives claimed in claim 3, and tocopherol acetate since all ingredients are well known for their use in skin care preparations and useful for compositions for skin care as disclosed in Bissett et. al. All

the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, one of ordinary skill in the art would have reasonably expected that a composition comprising hexamidine in combination with other cosmetic/skin care actives would have resulted in beneficial effects as a skin care composition.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted September 28, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the previously submitted declaration of Rosemarie Osborne demonstrates unexpected results for the claimed combination. Specifically, the combination of hexamidine and vitamin B3 is shown to produce various super-additive up-regulation and down-regulation of certain genes in an *in vitro* model of human skin. According to MPEP 716.02, "Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)" and also " The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter.

1992) (Ex parte C, 27 USPQ2d 1492) In particular, the board concluded in *Ex parte* C, "We remind appellant that in submitting evidence asserted to establish differences and/or unobvious results sufficient to dissipate a *prima facie* case of obviousness, there is a burden on the patent applicant to establish not only that the differences in results achieved are in fact "unexpected and unobvious" but also to establish that the differences are of practical significance." (p. 1947 paragraph 4) In this decision, the Board determined that various unexpected characteristics of a plant were not persuasive to overcome a *prima facie* case of obviousness because the applicant had not established the significance and relative importance of the cited characteristics.

In the instant case, Applicant has screened the claimed composition for its effect on a panel of over 20000 genes and an untold number of uncharacterized expressed sequences, and identified 342 genes for which the combination of hexamidine and vitamin B3 produce a superadditive effect on expression. Declarant then speculates that because a number of these genes are involved in gluconeogenesis and RNA splicing, they might be useful in treating a number of skin conditions. However, gluconeogenesis and RNA splicing are ubiquitous processes fundamental to cellular metabolism. Declarant's assertion that these genes are involved in "preventing, retarding, and/or treating the appearance of skin conditions such as: fine lines and/or wrinkles; hyperpigmentation such as post-inflammatory hyperpigmentation; sagging; skin atrophy;, skin dryness; dark trudge circles and puffy eyes; sallowness; desquamation, exfoliating, and/or increasing skin turnover;, enlarged pores; and/or oily and/or shiny appearance of skin," is based on nothing more than the statement that,

"glucose is a fundamental compound that is essential to processes that regulate the condition of mammalian keratinous tissues such as skin," and furthermore that "processes that increase mRNA splicing and decrease protein catabolism are fundamental to processes that regulate the condition of mammalian keratinous tissues such as skin." These statements overlook the fact that glucose is a fundamental compound in all cells and RNA splicing and protein catabolism are fundamental to every cellular process as they are essential to gene regulation and expression. Practically any physiological change in the tissue could conceivably be associated with either up-regulation or down-regulation of these processes. Therefore the discovery that expression of these particular genes is affected by the claimed composition says nothing as to what biological effect is being produced, or even whether the modulation of expression of these genes produces a beneficial effect, a harmful effect, or no significant effect at all. Declarant's speculation as to the potential usefulness of these gene regulation processes is merely a statement of opinion by an interested party and therefore not persuasive to establish that the disclosed data are of any practical significance.

In short, Applicant has done nothing more than mine a sufficiently large data set (essentially all known human genes) for a number of statistically significant correlations (which amount to less than 2% of the genes screened) without establishing whether these genes are indicative of any useful *in vivo* effect. These genes are no more or less likely to be involved in the recited list of therapeutic effects than any arbitrary collection of 300 or so genes. One of ordinary skill in the art would certainly expect that mining

any sufficiently large data set will eventually turn up a statistically significant result. A finding of unexpected results requires that this result be shown to be of practical significance. Therefore the rejection is deemed proper and made **FINAL**.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett et. al. (U.S. Patent No. 6,284,802; of record in previous action) as applied to claims 1-5, 21, 23-24, 26 and 28-36 above, and further in view of Castiel et. al. (US 2003/0176366 A1, of record in previous action)

The disclosure of Bissett et al. is discussed above. Bissett et al. does not disclose a composition comprising ascorbyl glucoside.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1, Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside. (Page 4, Column 2, Example 3) These compositions are useful for improving the suppleness and appearance of the skin, treating wrinkles and fine lines, and combating aging. (p. 3 paragraph 45)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add ascorbyl glucoside to the compositions of Bissett et al. One of ordinary skill in the art would have been motivated to do so because both compositions are disclosed to be useful for the same purpose, namely improving the appearance and quality of the skin. One of ordinary skill in the art would reasonably have expected

success because combining two known prior art compositions is ordinary and routine for one of ordinary skill in the art.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted September 28, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Bissett et al. above and are not found persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL3**.

Claims 1, 3, 5, 23, 24, 26, 28, 29, 31, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. (US patent 6589514, of record in previous action) in view of Flick et. al. (Cosmetic Additives - An industrial Guide, Pages 647-648, 652; Of record), Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

Jensen et. al. discloses compositions comprising hexamidine (0-1%), and carriers including water, seed oil and vegetable oil. The presence of water, fruit juice, glyceryl stearate, seed oil, vegetable oil and PEG-40 stearate is expected to form an emulsion in the form of a water-in-oil or oil-in-water or a combination of both.

Furthermore, Jensen et. al. discloses the use of panthenol in a skin care composition. Example two of Jensen (column 11, lines 35-68) is a dermatological

composition including *Morifinda citrifola* fruit juice, the retinoid retinyl palmitate and BHT. *Morifinda citrifola* fruit juice is disclosed to comprise many different active agents including antioxidants and essential fatty acids. (column 8 lines 34-42)

Jensen et. al. does not expressly disclose a composition comprising vitamin B3 or panthenol in combination with a hexamidine compound and a carrier. (Column 11, Example 2, line 53-64).Jensen et. al. further discloses the use of tocopheryl acetate (Column 11, Example 2, line 58-60, Example 4, lines 43, Example 1).

Flick et. al. in his cosmetic handbook discloses that panthenol is used in skin care products as a quick deep penetrating moisturizer, that aids in tissue repair and promotes normal keratinization. (Cosmetic Additives- An Industrial Guide, Page 648, Paragraph titled "Role in skin care products"). Flick et. al. further discloses commercial sources of panthenol compounds. (Page .647). Flick et. al. further discloses commercial sources of various forms of vitamin E including a-tocopherol acetate. (Page 652) As such, panthenol and a-tocopherol acetate are considered as ingredients well known by one of ordinary skill in the arts in the cosmetic, pharmaceutical and skin care industry.

Gensler HL et. al. discloses that topical nicotinamide (also known by the chemical name niacinamide) prevents systemic immunosuppression and skin tumorgenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that immunoenhancement by nicotinamide results in prevention of phtocarcinogenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that e-tocopherol can also contribute to inhibition of photoimmunosuppression and photocarcinogenesis. (Page 161, Column 2, second paragraph). One or ordinary

skill in the art would recognize protecting against UVB as a beneficial in a skin care composition.

Oblong et. al. discloses that vitamin B3 compounds can have beneficial effects such as improving tactile discontinuities of the skin. Oblong discloses the use of 2-5% niacinamide. (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, vitamin B3, panthenol, a-tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising a-tocopherol acetate, hexamidine and discloses panthenol in skin care compositions and Flick et. al. discloses panthenol and e-tocopherol acetate as commercially available cosmetic additives and Gensler et. al. discloses that topical application of niacinamide and a-tocopherol can contribute to protection against UVB rays and Oblong et. al. discloses the beneficial effects of niacinamide such as regulating visible and tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and a-

tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted September 28, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that there would be no reasonable expectation of success in modifying the disclosure of Gensler et al. by administering nicotinamide as part of the topical composition of Jensen rather than in acetone solution, and combining it with the various additional ingredients present in the composition of Jensen et al. However, although there are differences between the acetone solution described by Gensler et al. and the topical emulsions described by Jensen et al., the purpose of the two compositions is the same, namely to apply active ingredients to the skin. Thus one of ordinary skill in the art would have reasonably expected that adding an active ingredient such as nicotinamide to the compositions of Jensen et al. would result in the delivery of this active ingredient to the skin, especially since Jensen et al. already discloses that these emulsions are suitable for delivering a wide variety of other active agents to the skin. Regarding the combinability of nicotinamide with the various ingredients of the composition of Jensen et al., one of ordinary skill in the art would have expected that a combination of different active

ingredients would not interfere with their respective functions absent evidence to the contrary.

Applicant further argues that the declaration previously presented by Rosemarie Osborne demonstrates unexpected results for the claimed compositions of vitamin B3 and hexamidine. This argument is the same as the one made above with respect to the rejection over Bissett et al., and is not found to be persuasive for the same reasons.

Therefore the rejection is deemed proper and made **FINAL**.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Gensler et. al. (of record in previous action), Mammone et. al. (WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

The disclosure of Jensen et. al. is disclosed above. Jensen et. al. does not expressly disclose the use of vitamin B3 compounds, in particular niacinamide or the use of N-acetyl glucosamine in skin care compositions. The disclosure of Gensler et. al. is discussed above.

Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions used for exfoliation and moisturization. (Abstract, Page 2, lines 14-17). The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, N-acetyl glucosamine, niacinamide and a carrier because Jensen et. al. discloses skin care

compositions comprising hexamidine and Gensler et. al. discloses that topical application of niacinamide can contribute to inhibition of photoimmunosuppression and photocarcinogenesis and Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions as an exfoliant and Oblong discloses the use of niacinamide against tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and a-tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted September 28, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection over Jensen et. al. in view of Flick et. al. Gensler et.

al. and Oblong et. al. above and are not found persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Castiel et. al. (US 2003/0176366 A1, of record in previous action), (WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; of record in previous action).

The disclosure of Jensen et. al. is discussed above

Jensen et. al. does not expressly disclose the use of ascorbyl glucoside in skin care compositions or a 0.01 to 10% of a vitamin B3 compound.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1, Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside (Page 4, Column 2, Example 3).

The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, a retinoid, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, carriers and a retinoid and Castiel et. al. discloses the use of ascorbyl glucoside in skin care compositions to increase epidermal lipogenesis.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, a retinoid, and a carrier and Castiel et. al. discloses that the use of ascorbyl glucoside in skin care compositions increases epidermal lipogenesis.

Therefore, one of ordinary skill in the art would have reasonably expected that the use ascorbyl glucoside in a skin care composition comprising hexamidine, a retinoid and a carrier would result in substantially similar or improved skin care composition.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

Response to Argument: Applicant's arguments, submitted September 28, 2009 with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Castiel et al. does not address the combination of hexamidine and vitamin B3 as discussed above with regard to claim 1. Applicant's arguments are the same as those made with respect to Jensen et al. in view of Flick et al. in view of Gensler et al. in view of Oblong et al. above, and are found not persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 23, 26, 31, 35, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 11, 12, and 20 of U.S. Patent No. 10/841193. (Published as US publication 2004/0228820, cited in PTO-892, commonly assigned with the instant application, herein referred to as '193) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 and 11-18 of '193 anticipate or render obvious the claimed invention.

Claims 1 and 4 of '193 are drawn to a skin care composition containing 0.001% to about 10% of an amidine. Claim 3 defines the amidine as hexamidine with an alkane polyol that is reasonably considered to be a dermatologically acceptable carrier. Claims 11 and 12 of '193 further comprise additional skin care ingredients including BHT, phytosterols, a vitamin B_3 compound, panthenol, and retinoids. Claim 20 of '193 is drawn to a composition that is a water in silicone emulsion. With regard to the specific

amount of vitamin B3 in instant claim 26, it would have been obvious to one of ordinary skill in the art to choose an appropriate amount of active agent. Therefore claims 1, 3, 4, 11, 12, and 20 of '193 anticipate or render obvious the claimed invention.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the provisional rejection be held in abeyance until the application '193 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained.

Claims 1-5, 21-24, 31, 32, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-13, and 18 of copending Application No. 10/977848. (Published as US patent publication 2005/0214332, cited in PTO-892, herein referred to as '848) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 5-13, and 18 of '848 anticipate the claimed invention.

Claim 1 of '848 is drawn to a composition comprising at least two skin care active compounds including sugar amines, vitamin B3 compounds, phytosterols, and hexamidines. Dependent claims 5-13 specify that the compounds include N-acetyl glucosamine and niacinamide, and that he composition is an oil-in-water or silicone-in-water emulsion. Claim 18 is drawn to a composition further including retinoids, peptides, and butylated hydroxytoluene (the compound of instant claim 36) With regard to the specific amount of vitamin B3 in instant claim 26, it would have been obvious to one of ordinary skill in the art to choose an appropriate amount of active agent.

Therefore claims 1, 5-13, and 18 of '848 anticipate or render obvious the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the provisional rejection be held in abeyance until the application '848 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained.

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, and 4-16 of copending Application No. 10/152,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '924 application is directed to an article comprising a skin care composition comprising hexamidine, niacinamide (vitamin B3) and a carrier. The claims herein are directed to a composition comprising hexamidine, vitamin B3 and a carrier. Thus, claims 1-3 are deemed anticipated by claims 1-2 and 4-16 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the

provisional rejection be held in abeyance until the application '924 issues in a patent.

As the present application has not been allowed, the provisional rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 23, 26, 31, 35, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 11, 12, and 20 of U.S. Patent No. 10/841193. (Published as US publication 2004/0228820, cited in PTO-892, commonly assigned with the instant application, herein referred to as '193) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 and 11-18 of '193 anticipate or render obvious the claimed invention.

Claims 1 and 4 of '193 are drawn to a skin care composition containing 0.001% to about 10% of an amidine. Claim 3 defines the amidine as hexamidine with an alkane polyol that is reasonably considered to be a dermatologically acceptable carrier. Claims 11 and 12 of '193 further comprise additional skin care ingredients including BHT, phytosterols, a vitamin B_3 compound, panthenol, and retinoids. Claim 20 of '193 is drawn to a composition that is a water in silicone emulsion. With regard to the specific amount of vitamin B3 in instant claim 26, it would have been obvious to one of ordinary skill in the art to choose an appropriate amount of active agent. Therefore claims 1, 3, 4, 11, 12, and 20 of '193 anticipate or render obvious the claimed invention.

Response to Arguments: Applicant's arguments/response filed January 8, 2009 have been fully considered but they are not persuasive. Applicants request that the provisional rejection be held in abeyance until the application '193 issues in a patent. As the present application has not been allowed, the provisional rejection is maintained and made **FINAL**.

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
1/6/2010